APR 1 1 2013

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter:

Draeger Medical Systems, Inc.
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Andover, MA 01810-2434
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Contact: Tom Ostrowski
Regulatory Affairs Specialist
E-mail: Tom.Ostrowski@draeger.com

Date Prepared: April 9, 2013

Device Names/Common Names/Classification Names:

Trade Name:	Infinity CentralStation® with Infinity M300®
Common Name:	Physiological Patient Monitoring Solution
Classification Name:	Monitor, Physiological, Patient (with arrhythmia detection or Alarms)
Product Code:	MHX
Class:	II
Regulation Number:	21 CFR 870.1025

Identification of Predicate or Legally Marketed Devices:

Infinity TeleSmart® Telemetry System cleared under 510(k) #K061379

2.1 Device Description:

The **Infinity CentralStation® (ICS)** is an information technology workstation that gathers and displays data for simultaneous central monitoring and critical care management of up to 32 patient monitors connected to the Infinity Network using an optional dual-screen configuration.

The ICS system consists of a central processing unit (CPU), one or two displays, a keyboard and a mouse. If an optional second monitoring unit is configured, an additional 32 patients can be monitored, for a total of 64 patients.

The ICS acquires and displays waveforms, parameters and alarms from Infinity bedside monitors and Infinity M300.

The **Infinity M300®** is a patient-worn transceiver that uses the ICS as the primary patient monitoring display and primary alarm source. The M300 provides continuous ambulatory monitoring for the following parameters:

- ECG including heart rate, arrhythmia, and ST segment analysis
- Pulse oximetry including SpO2, pulse plethysmogram waveform, and pulse rate

The M300 has a color display for displaying parameter information, waveforms, and alarms. It also has a rechargeable battery that can be charged using the bedside charger or the central charger.
The M300 is restricted to be used on one patient at a time.
The M300 also includes the following accessories:

- M300 bedside charger
- M300 central charger
- M300 programming kit

2.2 Indications/Intended Use:

The Infinity CentralStation (ICS) is intended for use by trained healthcare professionals for the purpose of centralized monitoring of adult, pediatric and neonatal patient data within the hospital or clinical environment. Centralized monitoring involves the display and management of data from networked patient monitors including the annunciation of visual and audible physiologic parameter alarms at a central monitoring workstation. Infinity CentralStation with REST ECG is intended for the production and interpretation of diagnostic electrocardiograms for adult and pediatric patients when connected to a monitor with diagnostic 12-Lead ECG monitoring enabled.

The Infinity M300 is intended for use with the ICS to monitor ECG and pulse oximetry on ambulatory and non-ambulatory adult and pediatric patients using wireless communication over the Infinity patient monitoring network.

The Infinity M300 with TruST is intended for 12-Lead ECG monitoring with a reduced set of electrodes. Reconstructed leads are intended for real-time assessment of ST segment changes.

Draeger Medical Systems, Inc.
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Contraindication:

The Infinity M300 is not compatible for use in an MRI magnetic field.

Predicate Devices:

- Infinity TeleSmart Telemetry system - K061379

Substantial Equivalence:

The modified Infinity CentralStation with Infinity M300 has been tested in accordance with applicable standards and internal design control procedures and was determined to be as safe and effective for its intended use as the predicate devices.

Biocompatibility:

Not applicable – The Infinity CentralStation with Infinity M300 and its components are not intended to contact the patient. If patient contact is made, it is transient with intact skin.

Sterilization:

Not applicable – The Infinity CentralStation with Infinity M300 and its components are not supplied sterile.

Standards and Guidance:

Electromagnetic Compatibility:

> IEC 60601-1-2: 2007 Medical electrical equipment. General requirements for basic safety and essential performance. Collateral standard. Electromagnetic compatibility. Requirements and tests.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 11, 2013

Draeger Medical Systems Inc.
c/o Mr. Tom Ostrowski
Regulatory Affairs Specialist
6 Tech Drive
Andover, MA 01810

Re: K130711
Trade/Device Name: Infinity CentralStation with Infinity M300
Regulatory Number: 21 CFR 870.1025
Regulation Name: Patient Physiological Monitor (with arrhythmia detection or alarms)
Regulatory Class: II (two)
Product Code: 74 MHX
Dated: March 13, 2013
Received: March 19, 2013

Dear Mr. Ostrowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Dräger

K130711

510(k) Number (if known): _____

Device Name: Infinity CentralStation with Infinity M300

Indications for Use:

The Infinity CentralStation (ICS) is intended for use by trained healthcare professionals for the purpose of centralized monitoring of adult, pediatric and neonatal patient data within the hospital or clinical environment. Centralized monitoring involves the display and management of data from networked patient monitors including the annunciation of visual and audible physiologic parameter alarms at a central monitoring workstation. Infinity CentralStation with REST ECG is intended for the production and interpretation of diagnostic electrocardiograms for adult and pediatric patients when connected to a monitor with diagnostic 12-Lead ECG monitoring enabled.

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Contraindication:

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Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Owen P. Faris -S
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